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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/701,660	11/04/2003	William I. Stopperan	WPCI-Nonprov	7508

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EXAMINER
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LABAZE, EDWYN

ART UNIT	PAPER NUMBER
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2876

DATE MAILED: 10/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/701,660

Applicant(s)

STOPPERAN ET AL.

Examiner

EDWYN LABAZE

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-69 and 108 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 15, 23-26, 43, 46, 52, 53, 59, 60, 66-69 and 108 is/are rejected.
- 7) ☐ Claim(s) 10-14, 16-22, 27-32, 44, 45, 47-51, 54-58 and 61-65 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>11042003</u> . | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

1. Receipt is acknowledged of IDS filed on 11/04/2003.
2. Receipt is acknowledged of pre-amendments filed 11/04/2003, wherein claims 70-107 and 109-253 were cancelled.
3. Claims 1-69 and 108 are presented for examination.
4. This application claims the benefits of 60/423,955 files on 11/04/2002.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-3, 7-9, 23-26, 33-37, 41-43, 46, 52-53, 59-60, 66-68 are rejected under 35 U.S.C. 102(b) as being anticipated by Lappe (U.S. 6,036,092).

Re claims 1, 33-35, and 67-68: Lappe discloses on-site machine readable assaying arrangement, identifying a specimen donor {herein an individual/patient through a name, social security, and the like} with a specimen donor identification information {such a barcode 42} item (col.8, lines 40+); adequately specifying a specimen {such urine, blood, DAN and the like} related event identifier (col.3, lines 4+); associating the specimen donor identification information item with the specimen related event identifier; and generating a unique specimen identification information item {herein a bar code 42} in response to the step of associating the

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specimen donor identification information item with the specimen related event identifier (col.6, lines 50+).

Re claim 2: Lappe teaches a system and method, wherein means of generating a unique specimen identification information item in response to the step of associating the specimen donor identification information item with the specimen related event identifier comprises the step of generating a unique specimen identification information item 42 by performing the step of associating the specimen donor identification information item with the specimen related event identifier (col.8, lines 15).

Re claims 3 and 37: Lappe discloses a system and method, wherein means of identifying a specimen donor with a specimen donor identification information item comprises the step of identifying a specimen donor with a social security number (col.8, lines 42).

Re claims 7 and 36: Lappe teaches a system and method, wherein generating a unique specimen identification information item {bar code 42} comprises the step of generating a character-based, substantially contiguous specimen identification information item 32 (col.4, lines 35+).

Re claims 8, 23, 25, 42-43, 52-53, and 59: Lappe discloses a system and method, further comprising means of rendering the specimen donor identification information item not immediately discernible {herein interpreted as machine-readable pattern} (col.4, lines 65+; col.6, lines 55+).

Re claims 9 and 66: Lappe teaches a system and method, further comprising means of associating a discernment process {herein using a decoder 54b for decoding the encoding

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characters} specificity information item with the not immediately discernible specimen donor identification information item (col.8, lines 14+).

Re claims 15, 24, 26, 46, and 60: Lappe teaches a system and method, wherein the step of rendering said specimen donor identification information item not immediately discernible comprises the step of encrypting {herein means of encoding through the encoder 76} the specimen donor identification information item to create an encrypted specimen donor identification information item (col.4, lines 37+; col.9, lines 30+).

Re claim 41: Lappe teaches a system and method, wherein the specimen identifier is substantially contiguous {herein Lappe teaches that the encoded machine-readable data source may be provided to encode one or more characters/digits of information or data} (col.5, lines 57+).

### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
9. Claims 4-6, 38-40, 69, and 108 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lappe (U.S. 6,036,092) in view of Ogden et al. (U.S. 4,871,077).

The teachings of Lappe have been discussed above. Lappe further discloses that a volume of urine is collected and a highly sensitive screening test is performed (col.1, lines 42+), and a donor specimen may be given a collection container (col.9, lines 43+).

Lappe fails to specifically teach means of adequately specifying a specimen collection time, date, and time of day.

Ogden et al. discloses tamper resistant, tamper evident leak proof container, which includes teach means of adequately specifying a specimen collection time, date, and time of day (col.8, lines 40-51).

In view of Ogden et al.'s teachings, it would have been obvious to an artisan of ordinary skill in the art at the time the invention was made to employ into the teachings of Lappe means of adequately specifying a specimen collection time, date, and time of day so as to accurately define the age of the specimen. Furthermore, such modification would be very important in testing, usage, and storage practices by indicating the beginning of he life span from the date/time/day the specimen is collected. Moreover, such modification would have been an obvious extension as taught by Lappe, therefore an obvious expedient.

*Allowable Subject Matter*

10. Claims 10-14, 16-22, 27-32, 44-45, 47-51, 54-58, 61-65 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. The following is a statement of reasons for the indication of allowable subject matter: the prior art of record fails to specifically teach means of associating a character-based discernment code/decryption algorithm with the discernment process specificity information item to create a code representation information item, wherein the character-based discernment code represents the discernment process specificity information item. These limitations in conjunction with other limitations in the claimed invention were not shown by the prior art of record.

*Conclusion*

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Harrop (U.S. 6,598,796) teaches method and apparatus for aligning labels applied to a specimen collection container.

Cocola et al. (U.S. 6,832,722) discloses method and means for data management in a laboratory.

De Gaule et al. (US 2004/0166583) teaches method for determining and monitoring ageing of blood bags.

Auchinleck (US 2005/0184153) discloses apparatus and method for monitoring transfusion of blood.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to EDWYN LABAZE whose telephone number is (571) 272-2395. The examiner can normally be reached on 7:30 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Lee can be reached on (571) 272-2398. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

el  
Edwyn Labaze  
Patent Examiner  
Art Unit 2876  
September 20, 2006



**THIEN M. LE**  
**PRIMARY EXAMINER**